

### **DETAILED ACTION**

1. This action serves to replace the action filed 8/15/2008 as a result of the entering of the amendment filed 1/14/2008.

### ***Response to Amendment***

2. Acknowledgement is made of the amendment filed 1/14/2008. The claims have now been entered and the proceeding rejection reflects the entered claims.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 27, 29, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilboa (U.S. 2002/0193686) in view of Werp et al. (U.S. 6,015,414).**

Regarding **claim 33**, Gilboa teaches a method of navigating a probe including the steps of:

establishing a path in said lumen system from a topological representation of the lumen system (Para [0016], establishing a path would be necessary in order to move the catheter); determining a first position of said catheter in said path (Para [0028], "

...“probe” as used herein should be construed as including...a catheter”; Para [0016], “estimating a location of the target point-of-interest”) according to a position signal received of the first position of a distal portion of said catheter (Para [0016], “measuring a location of the probe relative to the reference frame”), and also determining a new position to which said catheter is to be moved based on said determined first position (Para [0016], “moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest”) and according to said path from said topological representation (Para [0016], “acquiring a plurality of projective images of at least a portion of the body cavity”);

operating a moving mechanism (see below) to move said catheter to a second position, according to said new determined position (Para [0016], “moving the probe, within the body cavity”);

receiving a position signal as said catheter is moved during said operating step (Para [0016], “measuring a location of the probe relative to the reference frame”), when said second position is substantially identical with said new determined position, determining a further new positions on said path to which said catheter is to be moved and, when said second position is not identical with said new determined position, determining at least one corrective movement for said catheter (Para [0016], “moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest”, see below);

and directing said moving mechanism to move said catheter according to said determined corrective movement (Para [0016], "moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest").

Para [0016] does not explicitly state using a "moving mechanism" to move the catheter. However, it is inherent to use some type of "moving mechanism" in order to move the catheter into and within the body, otherwise it would be impossible to move the catheter. It is well known in the art that this moving mechanism is traditionally simply the operator's hands, or, at other times, a mechanical moving mechanism can be used.

Para [0016] also supports the use of "corrective movements." In order to "minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest" (Para [0016]), it is necessary for the operator to move the catheter towards the point-of-interest with one or more corrective movements.

Gilboa teaches performing the medical procedure after the navigation of the catheter (Para [0066], "The present invention is of a method of performing invasive medical procedures ... such as stent deployment in a coronary artery").

Gilboa teaches the limitations as discussed above but fail to explicitly teach at least one corrective movement when the orientation does not match the slope of the path at a certain location. However, in the same field of endeavor, Werp et al. teach at least one corrective movement when the orientation does not match the slope of the path at a certain location (Fig. 4). Therefore, it would have been obvious to a person of

ordinary skill in the art at the time of the invention to modify Gilboa to include the correction procedure in order to more accurately navigate the catheter to a destination (col. 4, lines 22-62).

Regarding **claim 32**, Gilboa teaches moving a catheter in the longitudinal direction. Such a movement is a necessary action when pushing/moving/guiding a catheter to a location of interest.

Regarding **claim 27**, Gilboa further teaches the topological representation being produced by indicating an origin and a destination on an image of at least a portion of said lumen, in a coordinate system respective of said body.

(Para [0074], "...the user changes the coordinates of the point represented by the icon until the icon coincides with the projection of the point-of-interest on each of the images."; Para [0076], "...only icons representing the locations of the points-of-interest are displayed on a display unit ...along with an icon representative of the true location of the catheter relative to the points of interest"); Para [0077], "if so desired, the points of interest may be displayed superposed on one of the images, from the point of view at which that image was acquired").

Regarding **claims 29 and 30**, Gilboa further teaches the invention wherein said image is produced by imaging said at least one portion, at least one unparallel imaging planes, one of which is closest to said predetermined path among a plurality of other image planes (Para [0080]).

Para [0080] discloses, "...several images of coronary artery tree 28 are acquired...from several angles; also see figure 3 for "unparallel imaging planes".

Regarding claim 29, among the several images, a "closest image" is inherently and necessarily acquired, "closest" being relative to the distances of the other images.

Regarding claim 30, Gilboa's technique of acquiring images of the coronary artery tree from several angles implies the images all contain at least a portion of the lumen system of interest, thereby inherently disclosing an "overlap" within the images.

**5. Claims 18, 26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilboa in view of Werp et al., further in view of Strommer et al. (U.S. 2001/0031919 A1).**

**Regarding claim 18**, Gilboa teaches the limitations as discussed above. Gilboa does not teach updating at least one of said topological representation according to an organ timing signal of an organ timing monitor coupled with a monitored organ of said body. However, Strommer et al. teach the real-time reading of an organ timing signal for real-time visualization of the inspected organ which is then used to update the 3D image of the body (Para [0046]; also see claim 26). Strommer et al. also goes on to teach controlling the said moving mechanism according to the updated topological representation (Para [0047]). Therefore, it would have been obvious to a person of ordinary skill in the art to modify Gilboa and Werp et al. to include the use of an organ timing monitor in the application of updating topological images as evidenced by Strommer et al. Such a modification would allow for a moving organ to be displayed in real-time (Para [0021]).

Regarding **claim 26**, Strommer et al. teach said display being used to display a superimposed topological representation on the display (paragraph 0047), which would require a 3D to 2D transformation in order for the 3D location to be matched to a 2D topological representation.

Regarding **claim 31**, Gilboa teaches the limitations as discussed above but does not explicitly teach the step of determining the shape of said distal portion. However, Strommer et al. teach the possibility of extrapolating the shape of the surgical tool through a reconstructed 3D image (Para [0076]). It would have been obvious to a person of ordinary skill in the art to modify Gilboa and Werp et al. to include the step of determining the shape of the distal portion of the catheter as evidenced by Strommer et al. Such a modification would create a more detailed image of the catheter so that the operator can more precisely navigate it.

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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